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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-13-0666]

Proposed Data Collections Submitted for
Public Comment and Recommendations

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call 404-639-7570 or send comments to Kimberly S. Lane, 1600 Clifton Road, MS-D74, Atlanta, GA 30333 or send an email to omb@cdc.gov.

invited (a) Whether Comments are on: the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d)

ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Written comments should be received within 60 days of this notice.

## Proposed Project

National Healthcare Safety Network (NHSN) (OMB No. 0920-0666), exp. 12/31/2015 - Revision - National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

## Background and Brief Description

The National Healthcare Safety Network (NHSN) is a system designed to accumulate, exchange, and integrate relevant information and resources among private and public stakeholders to support local and national efforts to protect patients and promote healthcare safety. Specifically, the data is used to determine the magnitude of various healthcare-associated adverse events and trends in the rates of these events among patients and healthcare workers with similar risks. The data will be used detect changes in the epidemiology of adverse events to resulting from new and current medical therapies and changing risks. The NHSN consists of six components: Patient Safety, Healthcare Personnel Safety, Biovigilance, Long-Term Care Facility (LTCF), Dialysis, and Outpatient Procedure.

The new Dialysis Component was developed in order to separate reporting of dialysis events from the Patient Safety Component. The new component will tailor the NHSN user interface for dialysis users to simplify their data entry and analyses processes as well as provide options for expanding the Dialysis Component in the future to include dialysis surveillance in settings other than outpatient facilities.

The new Outpatient Procedure Component was developed to gather data on the impact of infections and other outcomes related to outpatient procedures that are performed in settings such as Ambulatory Surgery Centers (ASCs), Hospital Outpatient Departments (HOPDs), and physicians' offices. Three event types will be monitored in this new component: Same Day Outcome Measures, Prophylactic Intravenous (IV) Antibiotic Timing, and Surgical Site Infections (SSI).

This revision submission includes two new NHSN components and their corresponding forms. The Dialysis Component consists of changes to three previously approved forms and the addition of four new forms. These new forms include component specific monthly reporting plan, prevention process measures monthly monitoring, patient influenza vaccination, and patient influenza vaccination denominator forms. The Outpatient Procedure Component consists of four new forms: component specific annual

survey, monthly reporting plan, event, and monthly denominators and summary forms.

Further, the breadth of organism susceptibility data required on all of the healthcare-associated infection (HAI) report forms (i.e., BSI, UTI, SSI, PNEU (VAP and VAE), DE, LTUTI, and MDRO Infection Surveillance) has been reduced for the purposes of streamlining, simplification, and removing undue burden where possible. Significant changes were made to the NHSN Biovigilance Component forms as a result of a subject matter expert and stakeholder working groups. This includes the removal of the monthly incident summary form. A brand new form was added (Form 57.600 - State Health Department Validation Record) to collect aggregate validation results that will be gathered by health departments when conducting facility-level state validation of NHSN healthcare-associated infection (HAI) data within their jurisdictions using the CDC/NHSN Validation Guidance and Toolkits.

Additionally, minor revisions have been made to 17 other forms within the package to clarify and/or update surveillance definitions.

The previously approved NSHN package included 48 individual collection forms; the current revision request adds nine new forms and removes one form for a total of 56 forms. The

reporting burden will increase by 542,123 hours, for a total of 4,104,776 hours.

## Estimated Annualized Burden Hours

				Avg.	
				Burde	
			No. of	n per	
			Respons	Respo	Total
		No. of	es per	nse	Burden
Type of		Respond	Respond	(in	(in
Respondents	Form Number and Name	ents	ent	hrs.)	hrs.)
	rorm number and name	CIICS	CIIC	1115./	1115./
Registered Nurse (Infection		2 000	1	F / C O	1.67
,	F7 100 NUON Designation Form	2,000	1	5/60	167
Preventionist)	57.100: NHSN Registration Form				
Registered Nurse	57 101 R	0 000	1	10/60	222
(Infection	57.101: Facility Contact	2,000	1	10/60	333
Preventionist)	Information				
Registered Nurse	57.103: Patient Safety		_		
(Infection	ComponentAnnual Hospital	6,000	1	30/60	3,000
Preventionist)	Survey				
Registered Nurse				_ ,	
(Infection	57.105: Group Contact	6,000	1	5/60	500
Preventionist)	Information				
Registered Nurse				,	
(Infection	57.106: Patient Safety Monthly	6,000	12	35/60	42,000
Preventionist)	Reporting Plan				
Registered Nurse					
(Infection	57.108: Primary Bloodstream	6,000	36	32/60	115,200
Preventionist)	Infection (BSI)				
Registered Nurse					
(Infection		6,000	72	29/60	208,800
Preventionist)	57.111: Pneumonia (PNEU)				
Registered Nurse	57.112: Ventilator-Associated				
(Infection	Event	6,000	144	22/60	316,800
Preventionist)					
Infection	57.114: Urinary Tract	6,000	27	29/60	78,300
Preventionist	Infection (UTI)	0,000	27	23/00	70,500
Staff RN	57.116: Denominators for				
	Neonatal Intensive Care Unit	6,000	9	3	162,000
	(NICU)				
Staff RN	57.117: Denominators for				
	Specialty Care Area	6,000	9	5	270,000
	(SCA)/Oncology (ONC)				
Staff RN	57.118: Denominators for				
	Intensive Care Unit	6,000	54	5	1,620,000
	(ICU)/Other locations (not	6,000	54	5	1,620,000
	NICU or SCA)				
Registered Nurse					
(Infection	57.120: Surgical Site	6,000	36	29/60	104,400
Preventionist)	/ / /	1	i	l	1
	Infection (SSI)				

	Procedure				
Laboratory	57.123: Antimicrobial Use and				
Technician	Resistance (AUR)-Microbiology	6 000	1.0	5/60	6 000
	Data Electronic Upload	6,000	12	5/60	6,000
	Specification Tables				
Pharmacy	57.124: Antimicrobial Use and				
Technician	Resistance (AUR)-Pharmacy Data		10	<b>5</b> / <b>6</b> 0	
	Electronic Upload	6,000	12	5/60	6,000
	Specification Tables				
Registered Nurse					
(Infection	57.125: Central Line Insertion	1,000	100	5/60	8,333
Preventionist)	Practices Adherence Monitoring	•		,	,
Registered Nurse	<u> </u>				
(Infection	57.126: MDRO or CDI Infection	6,000	72	29/60	208,800
Preventionist)	Form	.,			
Registered Nurse	57.127: MDRO and CDI				
(Infection	Prevention Process and Outcome	6,000	24	12/60	28,800
Preventionist)	Measures Monthly Monitoring	0,000		12,00	20,000
Registered Nurse					
(Infection	57.128: Laboratory-identified	6,000	240	15/60	360,000
Preventionist)	MDRO or CDI Event	0,000	210	13/00	300,000
Registered Nurse	Tible of oblivene				
(Infection	57.130: Vaccination Monthly	100	5	14	7,000
Preventionist)	Monitoring Form-Summary Method	100	5	14	7,000
Registered Nurse	57.131: Vaccination Monthly				
(Infection	Monitoring Form-Patient-Level	100	5	2	1,000
Preventionist)	Method	100	5		1,000
Registered Nurse	Meeriou				
(Infection		100	250	10/60	4,167
Preventionist)	57.133: Patient Vaccination	100	250	10/60	4,10/
Registered Nurse	57.137: Long-Term Care				
(Infection	Facility Component - Annual	250	1	45/60	188
Preventionist)	Facility Component - Annual Facility Survey	250	1	45/60	188
Registered Nurse	ractificy survey				
(Infection	E7 130. Inhoratory identified	250	8	15/60	500
Preventionist)	57.138: Laboratory-identified MDRO or CDI Event for LTCF	250	8	15/60	500
Registered Nurse	57.139: MDRO and CDI				
(Infection	Prevention Process Measures	250	12	5/60	250
Preventionist)	Monthly Monitoring for LTCF	250	12	3/60	250
Registered Nurse	Monthly Montheoling for lifer				
(Infection	57.140: Urinary Tract	250	9	27/60	1,013
Preventionist)	Infection (UTI) for LTCF	230	J	27/60	1,013
Registered Nurse	Infection (off) for fice				
(Infection	57.141: Monthly Reporting Plan	250	12	5/60	250
Preventionist)	for LTCF	<b>430</b>	12	5/60	∠50
Registered Nurse	TOT HICE				
(Infection	57.142: Denominators for LTCF	250	12	3	9,000
Preventionist)	Locations	230	14	3	9,000
Registered Nurse	57.143: Prevention Process			+	
(Infection	Measures Monthly Monitoring	250	12	5/60	250
Preventionist)	for LTCF	<b>∠</b> 50	12	3/60	∠30
	TOT DICE			+	
Registered Nurse (Infection		400	1	20/60	200
Preventionist)	F7 150. ITAC Approal Correct	400	1	30/60	200
-	57.150: LTAC Annual Survey				
Registered Nurse	E7 151. Dobob Approx 2	1,000	1	25/60	417
(Infection	57.151: Rehab Annual Survey				

Preventionist)					
Occupational	57.200: Healthcare Personnel				
Health	Safety Component Annual	50	1	8	400
RN/Specialist	Facility Survey	30		0	400
Occupational	ractificy survey				
_	57 000 H1+h D	F.0	0	10/60	7.5
Health	57.203: Healthcare Personnel	50	9	10/60	75
RN/Specialist	Safety Monthly Reporting Plan				
Occupational				,	
Health	57.204: Healthcare Worker	50	200	20/60	3,333
RN/Specialist	Demographic Data				
Occupational					
Health	57.205: Exposure to Blood/Body	50	50	1	2,500
RN/Specialist	Fluids				
Occupational					
Health	57.206: Healthcare Worker	50	30	15/60	375
RN/Specialist	Prophylaxis/Treatment				
Laboratory	57.207: Follow-Up Laboratory			15/50	
Technician	Testing	50	50	15/60	625
Occupational	57.210: Healthcare Worker				
Health	Prophylaxis/Treatment-	50	50	10/60	417
RN/Specialist	Influenza	30		-0,00	/
Medical/Clinical	IIIIIudiia				
Laboratory	57.300: Hemovigilance Module	500	1	2	1,000
Technologist	Annual Survey	500		2	1,000
	Ailluai Survey				
Medical/Clinical	57 201 H	F 0 0	1.0	1/60	100
Laboratory	57.301: Hemovigilance Module	500	12	1/60	100
Technologist	Monthly Reporting Plan				
Medical/Clinical					
Laboratory	57.303: Hemovigilance Module	500	12	1	6,000
Technologist	Monthly Reporting Denominators				
Medical/Clinical					
Laboratory	57.304: Hemovigilance Adverse	500	48	15/60	6,000
Technologist	Reaction				
Medical/Clinical					
Laboratory		500	12	10/60	1,000
Technologist	57.305: Hemovigilance Incident				
Staff RN	57.400: Outpatient Procedure				
	Component-Annual Facility	5,000	1	5/60	417
	Survey				
Staff RN	57.401: Outpatient Procedure				
	Component - Monthly Reporting	5,000	12	15/60	15,000
	Plan	,		,	,
Staff RN	57.402: Outpatient Procedure				
23411 141	Component Event	5,000	25	40/60	83,333
Staff RN	57.403: Outpatient Procedure			+	
DCALL IVI	Component - Monthly	5,000	12	40/60	40,000
		5,000	14	40/60	40,000
Dogiatored North	Denominators and Summary				
Registered Nurse	57 500 Outs-ti D' 3 '	6 000	1	1 25	10 500
(Infection	57.500: Outpatient Dialysis	6,000	1	1.75	10,500
Preventionist)	Center Practices Survey				
Staff RN	57.501: Dialysis Monthly	6,000	12	5/60	6,000
	Reporting Plan				
Staff RN	57.502: Dialysis Event	6,000	60	13/60	78,000
Staff RN	57.503: Denominator for	6,000	12	6/60	7,200
	Outpatient Dialysis				7,200
Staff RN	57.504: Prevention Process	600	12	30/60	3,600

	Measures Monthly Monitoring				
	for Dialysis				
Staff RN	57.505: Dialysis Patient	250	75	10/60	3,125
	Influenza Vaccination	250	,	10/00	3,123
Staff RN	57.506: Dialysis Patient				
	Influenza Vaccination	250	5	10/60	208
	Denominator				
Epidemiologist	57.600: State Health	152	50	15/60	1,900
	Department Validation Record	152	50	13/60	1,900
				Total	4,104,776

Ron A. Otten,

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